

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

C.A. No. 21-1015 (JLH)

PUBLIC VERSION

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**SAREPTA THERAPEUTICS, INC. AND
THE UNIVERSITY OF WESTERN AUSTRALIA'S OPPOSITION TO
PLAINTIFF/COUNTER-DEFENDANTS' SUMMARY JUDGMENT MOTIONS**

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TABLE OF ABBREVIATIONS

Abbreviation	Description
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'361 Patent	U.S. Patent No. 9,708,361
'092 Patent	U.S. Patent No. 10,385,092
'461 Patent	U.S. Patent No. 10,407,461
'106 Patent	U.S. Patent No. 10,487,106
'741 Patent	U.S. Patent No. 10,647,741
'217 Patent	U.S. Patent No. 10,662,217
'322 Patent	U.S. Patent No. 10,683,322
ASO	Antisense oligonucleotide
<i>Bold and Italic</i>	Emphasis added unless indicated otherwise
Br-1	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 1 Regarding Invalidity of the UWA Patents (D.I. 400)
Br-2	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 2 Regarding Infringement of Certain NS Patents (D.I. 403)
Br-3	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 3 Regarding Its Breach of Contract Claim (D.I. 406)
Br-4	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 4 Regarding No Anticipation (D.I. 410)
Br-5	NS's Memorandum of Law in Support of Its Motion for Partial Summary Judgment No. 5 Regarding No Inequitable Conduct (D.I. 415)
DMD	Duchenne muscular dystrophy
Ex. ____	Exhibit ____ ¹
MCA	Mutual Confidentiality Agreement (D.I. 2-1)
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Patents	U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322
PMO	Phosphorodiamidate morpholino oligomer

¹ Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Oppositions to Plaintiff/Counter-Defendants' Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Steven F. Dowdy, Ph.D. and Andrew Hirshfeld.

Abbreviation	Description
Popplewell 2010	Popplewell, et al., Comparative analysis of antisense oligonucleotide sequences targeting exon 53 of the human DMD gene: Implications for future clinical trials, 20 NEUROMUSCULAR DISORDERS 102–110 (2010)
Popplewell '212	U.S. Patent Publication No. 2010/0168212
POSA	Person of ordinary skill in the art
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
Sazani 2010	Sazani, P., et al., Safety Pharmacology and Genotoxicity Evaluation of AVI-4658, <i>Int'l J. of Toxicology</i> , 29(2):143-156 (2010)
Sazani '586	International Patent Publication No. WO 2010/048586
Sazani '591	U.S. Patent Application Publication No. US2010/0130591
RSOF	Responsive Concise Statement of Facts in Support of Sarepta Therapeutics, Inc. and the University of Western Australia's Opposition to NS's Summary Judgment Motions
UWA	Counter-Plaintiff The University of Western Australia
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827

I. INTRODUCTION

Sarepta and UWA respectfully request that the Court deny NS's motions for summary judgment regarding: (1) invalidity of the Wilton Patents; (2) infringement of certain NS Patents; (3) its breach of contract claim; (4) no anticipation of certain NS Patent claims; and (5) no inequitable conduct. Pursuant to the Court's Scheduling Order (D.I. 143, ¶13(b)), Sarepta and UWA concurrently respond to NS's concise statements of fact and offer concise counterstatements of fact for each of NS's motions.

II. LEGAL STANDARD FOR SUMMARY JUDGMENT

Summary judgment is appropriate only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). "As to materiality, the substantive law will identify which facts are material." *Id.* at 248. "[T]he dispute about a material fact is 'genuine,'" when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

"When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor." *MHL Custom, Inc. v. Waydoo USA, Inc.*, 654 F. Supp. 3d 329, 334 (D. Del. 2023) (citing *Scott v. Harris*, 550 U.S. 372, 378 (2007)).

III. OPPOSITION TO NS'S MOTION #1 (INVALIDITY OF WILTON PATENTS)

A. Summary of Argument

The central premise of NS's motion for summary judgment of invalidity—that the claims of the Wilton Patent recite an overly broad functional genus and lack written description and enablement—is wrong. The claims of the Wilton Patents recite a narrowly-tailored genus of ASOs,

defined by numerous structural features, in addition to their ability to induce exon 53 skipping. Because the Wilton Patents describe the relationship between the claimed function of exon 53 skipping and the common structural features that achieve it, the written description and enablement requirements are met. At a minimum, there are genuine issues of material fact for trial, precluding summary judgment.

Written description requires holistically evaluating facts from the perspective of a “person of ordinary skill in the art” (“POSA”). *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). For genus claims like those in the Wilton Patents, the written description requirement is met when the specification discloses *either*: (1) structural features common to the members of the genus such that a POSA can visualize or recognize the members of the genus (“structure-function correlation”) *or* (2) a representative number of species within the scope of the genus (“representative species”). *Id.* at 1350.

Here, the Wilton Patents satisfy the written description requirement by disclosing and claiming multiple **structural** features that define and limit the claimed antisense oligonucleotides (“ASOs”) to those that narrowly target the exon 53 “hot spot”—a discrete region within exon 53 of the dystrophin pre-mRNA that Dr. Wilton and his co-inventors determined is amenable to exon skipping. Because ASOs with these structural features narrowly target this hot spot through complementary base-pairing, a POSA would have understood that most, if not all, of these ASOs would induce exon 53 skipping. This **structure-function correlation**, supported by empirical evidence disclosed in the Wilton Patents, allowed POSAs to visualize or recognize members of the claimed genus of ASOs—as contemporaneously acknowledged by others. Ex. 12, SRPT-VYDS-0201529 ([REDACTED]). Despite bearing the burden of proof, NS ignores these structural requirements.

NS's enablement arguments fare no better. The amount of experimentation needed to practice the invention is at most reasonable, and not undue. *See Amgen Inc. v. Sanofi*, 598 U.S. 594, 612 (2023). Methods of making and testing ASOs were disclosed in the specification and well known in the art. Further, the mechanism by which ASOs induce exon skipping, through complementary binding to target sequences, was also known in the art. Because the Wilton Patents disclosed the exon 53 hot spot and structural features for ASOs targeting that hot spot, a POSA would have been able to practice the full scope of the claims without undue experimentation.

NS cites a handful of non-analogous cases to support its motion. But as discussed in detail below, those cases involved fundamentally different and unpredictable technologies, patent specifications that failed to resolve the unpredictability (i.e., no equivalent to the hot spot), and claims that were not limited by structural features correlating with activity. NS's motion ignores these important differences and should be denied for this additional reason.

B. Factual Background

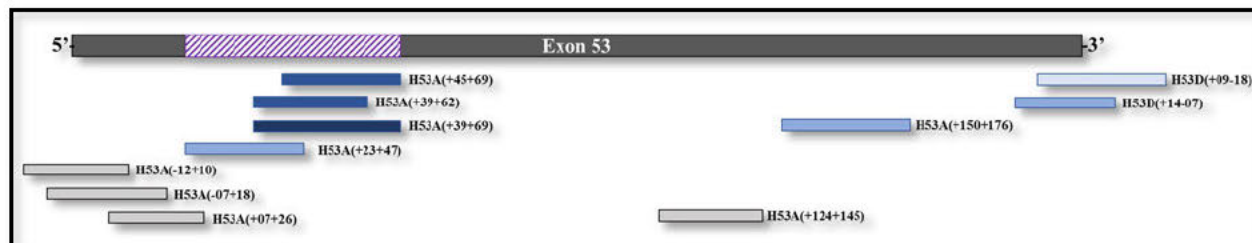
1. The Shared Specification of the Wilton Patents

DMD is a devastating fatal disease caused by mutations in the dystrophin gene. Br-1 at 2. Before the Wilton Patents were filed in June 2005, there was a long-felt need for treatments for DMD, including for patients with mutations amenable to exon 53 skipping. D.I. 427-2, ¶401. But it was unknown whether there was any specific region within human dystrophin that researchers could target with ASOs to induce exon 53 skipping, and thereby produce functional dystrophin. *Id.*, ¶333; RSOF ¶1.1.

Against this backdrop, the Wilton Patents, for the first time, identified a discrete region of human exon 53 between positions 23 to 69—i.e., a “hot spot”—that can be reliably targeted to

induce exon 53 skipping.² D.I. 427-1, ¶¶97-101; D.I. 427-2, ¶74; RSOF ¶¶1.2-1.3. Further efforts to optimize ASOs targeting this hot spot led to the identification of Sarepta's Vyondys 53[®], the first FDA-approved treatment for patients with mutations that are exon 53 skipping amenable. RSOF ¶1.4. NS later followed suit with Viltepso[®], [REDACTED] *Id.* For their pioneering work, the inventors of the Wilton Patents have received extensive scientific acclaim. *See* Ex. 13, SRPT-VYDS-0227837 ("Laboratory development of exon-skipping therapies began in the 1990s, including notably with MDA-funded work by Steve Wilton, PhD, and colleagues. Their work led to the invention of what would later become Exondys 51, Vyondys 53, and Viltepso."); Ex. 5, 197:15-198:4 ([REDACTED]).

The inventors of the Wilton Patents empirically identified the hot spot by testing a group of ASOs that are 20 to 31 bases in length and directed to various positions within exon 53. *See* D.I. 427-2, ¶74; Ex. 4, 124:6-18; D.I. 417-1 (Ex. 1), Table 39; RSOF ¶¶1.2-1.3. Among the tested ASOs were H53A(+23+47), H53A(+39+69), H53A(+39+62), and H53A(+45+69), collectively directed to nucleotides 23 to 69 of exon 53. D.I. 427-2, ¶74; Ex. 4, 124:19-125:22. Each of these overlapping ASOs induced exon 53 skipping. D.I. 417-1 (Ex. 1), Table 39; *see* Ex. 7, 222:13-223:21; Ex. 5, 152:11-153:19. The figure below illustrates the exon 53 hot spot (purple hash) and the various tested ASOs (with blue indicating exon skipping). RSOF ¶1.3.



² The term "hot spot" is a colloquial term used in molecular biology for an area where oligonucleotides have high activity. Ex. 11, 71:25-72:17. For purposes of its motion, NS does not contest that "[REDACTED]." Br-1 at 13 n.6.

The specification explains that “the invention provides antisense molecules capable of binding to a selected target to induce exon skipping.” D.I. 417-1 (Ex. 1), 4:44-46; D.I. 427-2, ¶¶467, 37 n.4. Consistent with the general knowledge in the art that exon skipping is “mediated by a true antisense mechanism,” the specification teaches that while the “antisense” molecules “need not be 100% complementary to that of its target sequence,” they must have “a sufficient degree of complementarity or precise pairing such that stable and specific binding occurs between the oligonucleotide” and its corresponding target region. D.I. 417-1 (Ex. 1), 25:18-38. The specification explains that a sufficient degree of complementarity avoids “non-specific binding of the antisense compound to non-target sequences.” *Id.*; D.I. 427-2, ¶¶37-38.

The specification also gives specific guidance on the structure of the inventive ASOs. In particular it identifies 12 bases as the minimum length of ASOs to induce exon skipping, and explains that ASOs of 20-31 bases would be more efficient. D.I. 417-1 (Ex. 1), 23:63-66; D.I. 427-2, ¶74. The specification also discloses particular backbone chemistries to use for the ASOs—2'-O-methyl phosphorothioate with uracil bases and “morpholino” with thymine bases. D.I. 417-1 (Ex. 1), Table 1A; D.I. 427-2, ¶74; Ex. 4, 125:23-127:12.

2. The Claims of the Wilton Patents

The claims of the Wilton Patents narrowly focus on a group of ASOs that target the exon 53 hot spot and induce exon 53 skipping. *See* D.I. 427-2, ¶68, Exhibit C; RSOF ¶¶1.6-1.8. Each of the claimed ASOs must share the following common structural features: (1) “antisense”; (2) “20 to 31 bases”; (3) “comprising a base sequence that is 100% complementary to consecutive bases of” (4) “a target region of exon 53 of the human dystrophin pre-mRNA”; (5) “the base sequence comprises at least 12 consecutive bases” of SEQ ID NO: 195; (6) “in which uracil bases are thymine bases”; and (7) “wherein the antisense oligonucleotide is a morpholino antisense oligonucleotide.” D.I. 417-1 (Ex. 1), claims 1-2; D.I. 417-1 (Ex. 2), claims 1-2; D.I. 417-2 (Ex. 3),

claims 1-2. In the case of the '851 Patent, the target regions of the claimed ASOs are further confined to positions 23 to 69 of exon 53 of the human dystrophin pre-mRNA.³ D.I. 417-1 (Ex. 1), claims 1-2; D.I. 248 at 20-25.

In addition to these structural requirements, the claims of the Wilton Patents require that the claimed ASOs induce exon 53 skipping. D.I. 417-1 (Ex. 1), claims 1-2; D.I. 417-1 (Ex. 2), claims 1-2; D.I. 417-2 (Ex. 3), claims 1-2. The claims, however, do not require any particular level of exon 53 skipping. Ex. 4, 127:13-128:6; D.I. 427-2, ¶117.

C. NS's Motion Regarding Lack of Written Description Should Be Denied

The test for written description is “whether the disclosure of the application relied upon reasonably conveys to [a POSA] that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad*, 598 F.3d at 1351. The test “requires an objective inquiry into the four corners of the specification from the perspective of a [POSA].” *Id.* That inquiry is a question of fact. *Id.* “[D]etermining whether a patent complies with the written description requirement will necessarily vary depending on the context” such as the “scope of the claims,” “the existing knowledge in the particular field,” and “the predictability of the aspect at issue.” *Id.* The written description requirement for a claimed genus—like a group of ASOs claimed here—can be satisfied when the specification discloses either: (1) structural features common to the members of the genus such that a POSA can visualize or recognize the members of the genus; or (2) a representative number of species within the scope of the genus. *Id.* at 1350.

³ NS argues that

Br-1 at 9-10.

See Ex. 7, 228:10-18, 228:25-229:6; see also *id.*, 229:18-230:21 (

).

Here, drawing all reasonable inferences in favor of Sarepta, the evidence demonstrates that the specification discloses sufficient common structural features to more than satisfy written description. At a minimum, a reasonable jury could reach those conclusions. NS's contrary arguments at most highlight genuine disputes of material facts for the jury to resolve, precluding summary judgment.

1. The Wilton Patents Disclose and Claim Structural Features Common to the Members of the Claimed Genus of ASOs

a. The Structure-Function Correlation Disclosed in the Specification Define the Claimed Genus of ASOs

The Wilton Patents provide ample support for the narrowly claimed genus of ASOs. Critically, the claims of the Wilton Patents set forth multiple *structural* requirements that the claimed ASOs must share. *See supra* § III.B.2. Indeed, the members of the claimed genus of oligonucleotides must be “antisense” (100% or nearly 100% complementary), “20 to 31 bases” (length), morpholino (backbone chemistry), have thymines rather than uracils (bases), have “a target region of exon 53 of the human dystrophin pre-mRNA” (the target region), and include “a base sequence that is 100% complementary to consecutive bases” of that target region and have “at least 12 consecutive bases” of SEQ ID NO: 195 (the base sequence). *See* D.I. 427-2, ¶127. For the '851 patent, the “target region” must also be within positions 23 to 69 of exon 53 of the human dystrophin pre-mRNA. D.I. 417-1 (Ex. 1), claims 1-2; D.I. 248 at 20-25. These structural features collectively target the claimed ASOs to the exon 53 hot spot. RSOF ¶¶1.6-1.7.

The specification likewise describes these claimed common structural requirements, including without limitation the use of “antisense” molecules, a preferred ASO length (20 to 31 bases), a minimum requirement of having at least 12 consecutive bases to a target region for inducing exon skipping, and morpholino ASOs with thymine bases. *See supra* § III.B.1; D.I. 417-1 (Ex. 1), 23:63-66, Table 1A; D.I. 427-2, ¶74. The specification further discloses that a high level

[REDACTED]

of complementarity is a common structural feature of exon skipping ASOs. D.I. 417-1 (Ex. 1), 25:21-38 (stating that exon skipping oligonucleotides must have “precise pairing” to ensure stable and specific binding and avoid “non-specific binding” to non-target sequences); RSOF ¶1.8. Because the claims require the claimed ASOs to “induce[] exon 53 skipping,” a POSA would have understood that the claimed genus is “a small genus of oligonucleotides that are highly complementary to the claimed exon 53 target region.” *See id.*; D.I. 427-2, ¶37 n.4.⁴

The structural requirements set forth in the claims of the Wilton Patents “collectively identify a limited group of candidate [ASOs], each of which a POSA would have been able to visualize from the disclosures of the Wilton Patents.” D.I. 427-2, ¶57. And a POSA reading the specification would have understood that most, if not all, of these ASOs would induce exon 53 skipping because the structural requirements in the claims target these ASOs to the exon 53 hot spot—the existence of which NS accepts for the purpose of its motion. *See* Br-1 at 13 n.6; D.I. 427-2, ¶¶67-68; Ex. 7, 24:9-14 ([REDACTED]), 55:4-10 (similar); RSOF ¶1.7.

The specification also provides empirical evidence supporting this structure-function correlation. *See* D.I. 427-2, ¶¶69-71. For example, H53A(+23+47)—the morpholino version of which NS admits falls within the claim scope of the Wilton Patents (Br-1 at 5)—was reported to induce exon 53 skipping. *Id.*, ¶¶69-70. Other nearby and overlapping ASOs, including H53A(+39+69), H53A(+39+62), and H53A(+45+69), also induced exon 53 skipping,

⁴ Contrary to NS’s argument (Br-1 at 8), the claimed genus of ASOs would be limited in scope regardless of whether “antisense” is given its plain and ordinary meaning of 100% or nearly 100% complementary (as applied by Dr. Dowdy) or completely ignored (NS’s position) (*infra* § III.C.1.c.ii), as a high level of complementarity is a common structural feature of ASOs intended to induce exon skipping. *See* D.I. 427-2, ¶37 n.4; D.I. 417-1 (Ex. 1), 25:21-38; *see* Sarepta’s Opposition to NS’s Motion to Exclude Opinions and Testimony of Steven F. Dowdy, Ph.D.

strengthening this correlation. *Id.*, ¶71. The written description requirement is therefore satisfied. At a minimum, a reasonable jury could conclude that the Wilton Patents disclosed “structural features common to the members of the genus so that [a POSA] can ‘visualize or recognize’ the members of the genus,” warranting denial of NS’s motion. *See Ariad*, 598 F.3d at 1350.

b. NS’s Contrary Contentions Are Legally and Factually Incorrect

i. NS Completely Ignores the Claimed Structural Features

NS argues that there is no structure-function correlation because the claimed ASOs “do not share ‘common’ base sequences.” *See* Br-1 at 12. But NS fails to explain why it is necessary for all claimed ASOs to have the *same base sequence* to satisfy the structure-function correlation when there are multiple structural features defining the claimed genus of ASOs including length, target region, complementarity, chemical backbone, and even at least 12 consecutive bases of SEQ ID NO: 195, *all* of which are ignored by NS. *See supra* § III.C.1.a; *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 652-53 (E.D. Tex. 2017), *aff’d* 739 F. App’x 643 (Fed. Cir. 2018) (although the claimed genus of PDE5 inhibitors do not share a common “chemical” structure, other common structural features such as a “core physical structure” can satisfy the structure-function correlation).

NS also ignores that every claimed ASO has a common sequence of bases complementary to a limited region of exon 53, the sequence of which was known since the 1980s. *See* D.I. 427-2, ¶68; D.I. 171 (Exhibit 43), ¶70. This structure-function correlation is akin to that considered in *Ajinomoto Co. v. Int’l Trade Commission*, 932 F.3d 1342 (Fed. Cir. 2019). There, the Federal Circuit found that genus claims directed to “a more potent promoter” satisfied the written description requirement because “promoters having fewer departures” from a known promoter sequence were “generally stronger than promoters with more departures from such a sequence.” *Id.* at 1359-60. As in *Ajinomoto*, a POSA here would have understood that ASOs with fewer

departures versus the exon 53 “hot spot” (i.e., 100% or nearly 100% complementarity) would be stronger than ASOs with more departures from that region. *See* Ex. 11, 24:9-25:19.

NS also argues that a POSA cannot “visualize the full scope of the claimed genus” because “[t]he specification provides no discussion whatsoever about why particular exon 53-directed [ASOs] worked.” *See* Br-1 at 11-12. But a POSA reading the specification would have understood the structure-function correlation, regardless of whether there is an explicit “discussion” of it. *See supra* §§ III.B.1, III.C.1.a; *Ariad*, 598 F.3d at 1351-52 (the written description requirement “requires an objective inquiry into the four corners of the specification from the perspective of a [POSA]” and “does not demand any particular form of disclosure”). Indeed, real-world evidence, ignored by NS, *confirms* that scientists in the field understood the disclosure of the exon 53 hot spot and the correlation between ASOs targeting the hot spot to exon 53 skipping. *See* Ex. 12, SRPT-VYDS-0201529; D.I. 427-2, ¶72. Even if NS disagrees, the evidence at a minimum raises a genuine dispute as to what a POSA would have understood from reading the Wilton Patents, precluding summary judgment. *Johns Hopkins Univ. v. 454 Life Scis. Corp.*, 183 F. Supp. 3d. 563, 574-78 (D. Del. 2016) (denying summary judgment for lack of written description in view of expert testimony “creat[ing] a genuine issue of material fact”).⁵

ii. NS’s Attacks Against the Significance of the Hot Spot Lack Merit and Raise Factual Disputes

NS also argues that the hot spot “cannot establish any structure-function correlation.” *See* Br-1 at 13-14. As an initial matter, NS accepted for purposes of its motion that the Wilton Patents

⁵ NS also contends that the Wilton Patents do not disclose the exact molecules that became Sarepta’s Vyondys 53[®] and NS’s Viltepso[®] products. *See* Br-1 at 6. [REDACTED]

[REDACTED] *See* Ex. 7, 27:18-28:8, 28:19-25; *id.*, 31:2-6 ([REDACTED]); Ex. 5, 124:11-125:2, 193:17-22. A POSA would have been able to visualize Sarepta’s Vyondys 53[®] and NS’s Viltepso[®] products based on the structural features recited in the claims of the Wilton Patents. *See* D.I. 427-2 (Exhibit C), Table 3 n.1, Table 7 n.2.

[REDACTED]

identified a “hot spot.” *Id.* at 13 n.6. This is a structure-function correlation: by definition, the hot spot links the claimed ASOs, which have structural features targeting the hot spot, with the claimed function of inducing exon 53 skipping. *See* Ex. 11, 71:25-72:17.

Regardless, NS’s arguments lack merit, and at a minimum, raise material factual disputes. For example, NS argues that many of the [ASOs] that would target the ‘hot spot’ are not in [the] claimed genus.” Br-1 at 13. This is irrelevant. That additional, unclaimed ASOs could also induce skipping does not undermine the correlation between the *claimed structural features* and the *claimed function* of inducing exon 53 skipping. *See Ariad*, 598 F.3d at 1350 (the structure-function correlation test focuses on “structural features common to the members of the [claimed] genus”).

While NS self-servingly characterizes the hot spot as “a starting point” or “mere wish or plan” (Br-1 at 14), Dr. Dowdy explained that the hot spot “shows that the claimed inventions work.” *See* D.I. 427-2, ¶148. The specification also provides empirical evidence, including H53A(+23+47) and other overlapping ASOs, that the claimed inventions actually work. *See id.*, ¶¶69-71. NS further argues that Dr. Dowdy [REDACTED]

[REDACTED]

[REDACTED] *See* Ex. 11, 44:11-15. At a minimum, this illustrates a genuine dispute of material fact as to whether and how the disclosed hot spot supports the claimed genus.

iii. The Patents in NS’s Cases Lack the Extensive Structural Disclosure of the Wilton Patents and Are Inapposite

NS is incorrect that *AbbVie*, *Juno*, and *Idenix* support summary judgment. *See* Br-1 at 4-5, 8, 11, 13-14 (citing *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir. 2014), *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021), and *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019)). The written description

[REDACTED]

inquiry is fact intensive and context specific, and the facts here are substantially different.⁶ *See Ariad*, 598 F.3d at 1351.

In each of these cases, the Federal Circuit found a lack of written description because the patents-in-suit failed to disclose “details regarding the characteristics, sequences, or structures” that correlated with the claimed functions. *See Juno*, 10 F.4th at 1339-40; *Idenix*, 941 F.3d at 1164 (the specification lacked “any indication as to *which* of those undisclosed [compounds] would be effective”); *AbbVie*, 759 F.3d at 1299 (the patentee’s expert “conceded that [the patents-in-suit] do not disclose structural features common to the members of the claimed genus”). That is not the case here. Before the Wilton Patents were filed, it was known that exon skipping was “mediated by a true antisense mechanism.” *See* D.I. 427-2, ¶37. Following the disclosure of ASOs identifying the exon 53 hot spot, a POSA would have understood “what makes [the claimed ASOs] effective” and “why” they induce skipping. *See id.*, ¶¶67-74; *cf. Idenix*, 941 F.3d at 1164.

NS also ignores the context of these cases, which involved technology that is substantially different from that at issue here. *See* Ex. 11, 186:2-15 [REDACTED]

[REDACTED] As the Federal Circuit observed in *Juno*, there is no common structure that makes antibodies bind to a particular target. *See Juno*, 10 F.4th at 1337. Similarly, the compounds claimed in *Idenix* allowed for “any imaginable substituent,” and the patent provided no distinction between substituents conferring the claimed function of treating infection versus those that did not. *Idenix*, 941 F.3d at 1155-56. In contrast, a POSA would have understood that the claimed ASOs of the Wilton Patents must be highly complementary to a limited region of the dystrophin pre-mRNA within the known sequence of exon 53, which the specification

⁶ The procedural posture of these cases is also different, as the Federal Circuit considered decisions rendered *after* the cases were presented to the jury. *See Idenix*, 941 F.3d at 1153-54; *Juno*, 10 F.4th at 1334; *AbbVie*, 759 F.3d at 1290.

teaches is critical for exon skipping. *See* D.I. 427-2, ¶¶47, 37 n.4; Ex. 11, 210:15-211:3 ([REDACTED]). These features allow a POSA to visualize each potential PMO, including its precise nucleotide sequence. *See* D.I. 427-2, ¶¶47, 57, Exhibit C. NS's attempt to analogize the claimed inventions to non-analogous art run afoul of the en banc Federal Circuit's express caution that the written description inquiry "will necessarily vary depending on the context." *Ariad*, 598 F.3d at 1351.

c. NS's Other Allegedly "Undisputed" Facts Are Disputed

To support its motion, NS identifies several additional facts that are purportedly "undisputed." *See* Br-1 at 6-8, 14-15. As discussed below, each is highly disputed, confirming that the written description question is appropriate for a jury.

i. The Parties Dispute the Unpredictability Pertaining to the Claimed Genus of ASOs

NS argues that it is "undisputed" that "the field of exon skipping is highly unpredictable." *See* Br-1 at 6-8. But based on the disclosure of the Wilton Patents, exon skipping within the exon 53 hot spot is predictable. As Dr. Dowdy explained, [REDACTED]

[REDACTED] D.I. 427-2, ¶¶104-105; RSOF ¶1.10; *see Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004) (the evaluation should involve "members of the group," not unclaimed compounds). A reasonable jury could conclude that once the work of the inventors of the Wilton Patents was disclosed, the art with respect to ASOs targeting the exon 53 hot spot became predictable.

To support its arguments, NS cites the prosecution history of the '851 Patent and an interference proceeding involving a non-asserted patent. *See* Br-1 at 6-8. But those statements were not specific to "exon 53-skipping," as NS wrongly contends, and instead concerned general

unpredictability in the art. *See* D.I. 428-6, SRPT-VYDS-0004790-95 (discussing ASOs directed to human exons 2, 29, 43, 46, 48, 50 and mouse exon 23); D.I. 427-23, 4-9 (similar). Statements about the predictability of skipping other exons or skipping outside the exon 53 hot spot do not address “the predictability of the aspect at issue”—the **claimed** exon 53 skipping ASOs. *See Ariad*, 598 F.3d at 1351; *Bilstad*, 386 F.3d at 1125.

NS also ignores the context of Sarepta’s statements. The interference arguments involved a different patent, with claims of different scope. *See* D.I. 427-23, 1, 9-10. The prosecution arguments responded to an obviousness rejection, which evaluated the pending claims **without** the benefit of the Wilton Patents. *See* D.I. 428-6, SRPT-VYDS-0004783. Those arguments are not relevant as to what a POSA would have understood with respect to exon 53 targeting ASOs **after** the disclosure of the Wilton Patents. *BASF Plant Sci., LP v. Commonwealth Sci. & Indus. Rsch. Org.*, 28 F.4th 1247, 1265 n.4 (Fed. Cir. 2022) (“What the specification at issue describes to a relevant artisan as the inventions possessed by the inventors presents a distinct question from what a relevant artisan would have found obvious from the prior art without the specification.”).

NS’s passing reference to judicial estoppel does not hold water. Judicial estoppel applies only when a party takes a position “clearly inconsistent” with a position taken in an earlier case. *New Hampshire v. Maine*, 532 U.S. 742, 750 (2001). But the statements relied on by NS were presented under a **different** legal theory at a **different** point in time (obviousness during prosecution) and a **different** patent (interference proceeding). There is nothing “mutually exclusive” between those arguments and the contention that ASOs targeting the hot spot disclosed in the Wilton Patents, like those claimed, would predictably induce exon 53 skipping. *See Cleveland v. Pol’y Mgmt. Sys. Corp.*, 526 U.S. 795, 797 (1999) (“two seemingly divergent statutory contentions are often consistent, each with the other”).

[REDACTED]

Citing the testimony of Dr. Dowdy, NS also contends that “expert testimony in this case

[REDACTED]

[REDACTED] Br-1 at 7-8 (citing Ex. 11, 209:19-23, 192:1-4). To the contrary, Dr. Dowdy [REDACTED]

[REDACTED] Ex. 11, 209:19-23, 192:1-4. Dr. Dowdy’s testimony illustrates at the very least a genuine dispute of material fact.

ii. The Parties Dispute the Nature and Size of the Claimed Genus of ASOs

NS contends that “[t]here is no genuine dispute that the [Wilton] Patents’ broadly claimed functional genus is vast.” Br-1 at 8. Not so. As NS acknowledges, the parties’ experts offered competing analyses as to the number of PMOs potentially encompassed by the Wilton Patents. *Id.* Indeed, as Dr. Dowdy explained and *NS’s expert Dr. Hastings acknowledges*, NS ignores multiple claim limitations in evaluating claim scope, including that the claimed oligonucleotides must be “antisense,” “induce[] exon 53 skipping,” and have “a target region of exon 53 of the human dystrophin pre-mRNA”—which must be further confined to nucleotides 23 to 69 in the case of the ’851 Patent. D.I. 427-2, ¶33; D.I. 427-5, ¶45; Ex. 4, 96:20-97:5 (Dr. Hastings testifying that [REDACTED]); RSOF ¶1.9. In contrast, Dr. Dowdy accounts for all of the requirements disclosed and claimed in the Wilton Patents, opining that the claims of the Wilton Patents are narrowly tailored to a “limited” group of ASOs, “each of which a POSA would have been able to visualize from the disclosures of the Wilton Patents.” See D.I. 427-2, ¶¶56-57, Exhibit C. Taking all inferences in favor of Sarepta, a reasonable jury could conclude that the claimed genus of ASOs is limited.⁷ See *id.*

⁷ In an attempt to sidestep this dispute, NS wrongly moves to exclude Dr. Dowdy’s opinions, arguing that Dr. Dowdy applies an “improper and late-offered limiting claim construction for

NS's contention that, under *Idenix*, the “potential genera remain large by any measure” is similarly misplaced. *See* Br-1 at 8. In *Idenix*, the size of the genus was critical because the specification provided “no indication that any [compounds] outside of those disclosed” could confer the claimed function of treating a viral infection. 941 F.3d at 1164. In contrast, a POSA here would have known that most, if not all, ASOs meeting the structural requirements of the claims would induce exon 53 skipping in view of the disclosure of the Wilton Patents. *See* D.I. 427-2, ¶¶66-74; *see supra* §§ III.B.1, III.C.1.a. In other words, even if the genus was deemed large, there is adequate written description support because the common structural features correlate with the function of exon 53 skipping. *See UroPep*, 276 F. Supp. 3d at 646, 652-53 (even though the claimed genus was “very large,” the written description requirement was met in view of “a common physical structure shared by the members of that genus”).

**iii. The Parties Dispute the Value of the Testing
“Commissioned” by Dr. Hastings**

According to NS, testing “commissioned” by Dr. Hastings “establishes” that there is [REDACTED]

[REDACTED] Br-1 at 14-15. These [REDACTED]
[REDACTED] because a POSA would immediately recognize them as “purposefully designed to fail.” D.I. 427-2, ¶¶207, 224; *see In re Smythe*, 480 F.2d 1376, 1385-86 (C.C.P.A. 1973) (reversing the Board’s written description rejection because “it is almost always possible to so construe a claim as to have it read on inoperative embodiments,” which “would *never* be selected by [a POSA]”).

‘antisense oligonucleotide.’” Br-1 at 8. As explained in Sarepta’s concurrently filed opposition to NS’s *Daubert* motion, NS’s motion rests on an incorrect premise and is legally flawed.

The “ [REDACTED] litigation. Ex. 4, 106:22-108:24, 130:12-24; RSOF ¶1.11. They are not “antisense” oligonucleotides designed to induce exon 53 skipping because they depart from the plain and ordinary meaning of that term and the teachings of the specification. *See* D.I. 427-2, ¶¶202-209, 214-217. Indeed, [REDACTED] [REDACTED] *Id.*, ¶208. Others [REDACTED] [REDACTED] to the teachings of the Wilton Patents. *Id.*, ¶¶52-53, 207, 215.

Notably, NS ignores numerous real-world examples (i.e., not designed solely for litigation) that repeatedly confirm that ASOs meeting the claimed structural criteria induce exon 53 skipping. *See* D.I. 427-2, ¶¶75-94; RSOF ¶1.12. Indeed, Dr. Dowdy [REDACTED] [REDACTED] *See id.*, ¶211, Figures 13 & 14. Regardless, “[a]dequate written description does not require a perfect correspondence” but “more modestly . . . a ‘*correlation* between structure and function.’” *Ajinomoto*, 932 F.3d at 1360 (emphasis in original) (quoting *Ariad*, 598 F.3d at 1350). That a few litigation-designed oligonucleotides did not induce skipping does not negate the structure-function correlation disclosed in the Wilton Patents, and at most illustrates a dispute requiring resolution by the jury.

2. The Morpholino Version of H53A(+23+47) Is Representative of the Claimed Genus of ASOs

Because NS has not satisfied its burden in disproving the structure-function correlation, its written description motion fails, and the Court need go no further. *See Ariad*, 598 F.3d at 1350 (written description requirement is satisfied if a structure-function correlation is disclosed). But NS’s “representative species” analysis is similarly defective, constituting an independent reason for denial of summary judgment. NS’s arguments are premised on its theory that a single species

cannot be representative. *See* Br-1 at 1, 4-5, 10-11. But there are no “bright-line rules governing . . . the number of species that must be disclosed to describe a genus claim.” *Ariad*, 598 F.3d at 1351; *see also Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App’x 991, 995 (Fed. Cir. 2017) (“Even a single representative embodiment can support written description of a claimed genus.”).

Indeed, NS fails to explain why [REDACTED] [REDACTED] (*see* Br-1 at 9)—is not representative, particularly in view of additional overlapping ASOs that induced exon 53 skipping. NS relies on a newly created “Figure 1” (Br-1 at 10), which it purports shows the “overreach” of the claimed genus. This figure, however, finds *no* support from NS’s experts, and moreover highlights genuine issues of material fact. For example, NS fails to explain why alleged differences in skipping strength (e.g., “very faint skipping” versus “relatively high levels of skipping”) are relevant when the claims do not require any particular level of skipping. *See id.*; Ex. 4, 127:13-128:6. NS’s motion for summary judgment should be denied.

D. NS’s Motion Regarding Non-Enablement Should Also Be Denied

Enablement is a question of law based upon underlying factual findings. *See PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996). To be enabling, a specification “must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.” *Id.* “[T]he question of undue experimentation is a matter of degree.” *Id.* The specification “may call for a reasonable amount of experimentation to make and use a patented invention.” *Amgen*, 598 U.S. at 612. “What is reasonable in any case will depend on the nature of the invention and the underlying art.” *Id.*

If it is determined as a threshold matter that some experimentation is necessary to practice the claimed invention, the “*Wands*” factors can be used to gauge whether that experimentation is reasonable or undue. These include: (1) the breadth of the claims, (2) the nature of the invention,

(3) the relative skill of those in the art, (4) the state of the prior art, (5) the predictability or unpredictability of the art, (6) the amount of direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

1. There Is No Evidence That Any Experimentation Is Necessary

As a threshold matter, NS has not adduced evidence that any experimentation is necessary to practice the claimed inventions. *See Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1189 (Fed. Cir. 2014) (enablement analysis requires a challenger to “make the threshold showing that any experimentation is necessary to practice” the claimed invention). Every real-world ASO meeting the structural requirements of the claims induced exon 53 skipping. *See supra* § III.C.1.c.iii. Indeed, the only arguably contrary evidence that NS has offered is the testing of ASOs co-designed by NS’s counsel—ASOs purposely designed to fail. *See id.* A POSA would have dismissed these oligonucleotides as both outside the scope of the claims and inoperative in view of the teachings of the Wilton Patents, and thus no experimentation would be necessary. *Id.* Because NS has not even made this threshold showing, NS’s motion should be denied.

2. At a Minimum, a Genuine Dispute Exists as to Whether the Wilton Patents Enable the Full Scope of the Claimed Genus

As discussed below, the *Wands* factors demonstrate that the disclosure of the Wilton Patents is enabling. At a minimum, they reveal genuine disputes of material fact requiring resolution by a jury.

a. The Relative Skill in the Art Was High and Methods for Making and Testing ASOs Were Well Known

The relative level of those in the art is high: an advanced degree such as a Ph.D. or an M.D. and years of experience with ASOs for inducing exon skipping. D.I. 427-2, ¶232. Further, a POSA would be familiar with methods for making and testing ASOs, which were well known in the art.

See *id.*, ¶¶233-237; D.I. 427-5, ¶43. To the extent that NS argues to the contrary, the issue is at most disputed, and denial of summary judgment is warranted. See *Infinity Canopy, Inc. v. Import Fence Direct, Inc.*, No. CV 19-08427-AB (AGR), 2022 WL 1591702, at *4 (C.D. Cal. Mar. 17, 2022) (denying summary judgment in view of “a dispute of material fact concerning the requisite level of skill of a POSA”).

b. The Wilton Patents Provide Extensive Guidance on How to Make and Use the Claimed ASOs

Although “a patent need not teach, and preferably omits, what is well known in the art,” the Wilton Patents “provide[] extensive guidance for designing, synthesizing, and testing exon 53 targeting ASOs.” D.I. 427-2, ¶¶239-249; RSOF ¶1.5; *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

NS argues that the Wilton Patents purportedly “provide no explanation regarding why particular exon 53-directed [ASOs] worked” or “what structures in those exon 53-directed [ASOs] the inventors believed to be driving that exon 53-skipping function.” Br-1 at 18-19. But, as discussed above, a POSA reading the specification would have understood that ASOs targeting the exon 53 hot spot would induce exon skipping through complementary base-pairing to dystrophin. See *supra* §§ III.B.1., III.C.1.a. At a minimum, this evidence creates a genuine dispute of material fact. *Johns Hopkins*, 183 F. Supp. 3d at 574-75 (denying summary judgment on lack of enablement in light of expert testimony “create[ing] a genuine issue of material fact”).

For the same reasons, the snippets from Dr. Dowdy’s deposition cited by NS do not support its argument. See Br-1 at 18 (citing Ex. 11, 98:15-100:1). Contrary to NS’s characterization, Dr. Dowdy explained that as a general matter, [REDACTED]

[REDACTED]
[REDACTED] See Ex. 11, 98:15-100:1; D.I. 427-2, ¶¶246-247. He further

[REDACTED]

explained that [REDACTED]

[REDACTED]

[REDACTED] Ex. 11, 98:15-100:1, 100:2-18. Because the Wilton Patents supplied the “novel aspect of the invention” (the exon 53 hot spot), a reasonable jury could conclude that the enablement requirement is met. *See supra* §§ III.B.1., III.C.1.a; *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (“It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.”).

c. The Wilton Patents Resolved the Unpredictability with Respect to Exon 53 Targeting ASOs

A POSA would have understood that most, if not all, ASOs meeting the claimed structural criteria would induce exon 53 skipping in view of the disclosure of the Wilton Patents. Ex. 11, 44:11-15 ([REDACTED]). This is not a situation where the claimed ASOs can be identified only via trial-and-error experimentation.

NS’s contrary arguments are misguided. *See* Br-1 at 16-17. For example, NS again relies on statements concerning the purported “unpredictability” of exon skipping made during prosecution and in an interference (Br-1 at 17), but these arguments involved *different* legal tests, *different* exons, *different* timepoints, and/or *different* patents. *See supra* § III.C.1.c.i. NS also asserts that the Wilton Patents admit that trial-and-error experimentation is necessary (Br-1 at 16), but the specification merely acknowledges the importance of the empirical testing disclosed and reported in the patent that identified the exon 53 hot spot. *See* D.I. 427-2, ¶267.

The purported admissions from Dr. Dowdy further undermine NS’s arguments. Br-1 at 16-17 (citing Ex. 11, 24:9-25:19). As he explained, a [REDACTED]

[REDACTED]

[REDACTED]

See Ex. 11, 24:9-25:19. This is the *opposite* of unpredictable—a POSA would have understood how factors such as complementarity contribute to skipping activity, and the specification teaches the same. See D.I. 417-1 (Ex. 1), 25:21-38. Summary judgment is therefore inappropriate. See *PPG Indus.*, 75 F.3d at 1565 (no undue experimentation required when “the specification provides guidance in selecting the operating parameters that would yield the claimed result”).

d. Making and Using the Full Scope of the Claimed ASOs Was Routine

NS argues that “there is no genuine dispute of fact that the asserted claims broadly encompass at least many tens of thousands (if not many trillions) of candidate [ASOs] that meet the claims’ structural limitations.” Br-1 at 16. As discussed above, the size of the claimed genus is disputed. See *supra* § III.C.1.c.ii.

Regardless, the experimentation needed for practicing the full scope of the claims is reasonable. Indeed, “the experimentation required would have been routine and straightforward” because routine methods for synthesizing and evaluating ASOs were known and could be carried out in a parallel and high-throughput manner. See D.I. 427-2, ¶¶274-280; Ex. 11, 221:3-222:8. Further, a POSA would have followed the guiding principle of synthesizing and screening ASOs by starting with those that were fully complementary, strategically introducing mutations as appropriate. See Ex. 11, 220:10-23; D.I. 427-2, ¶278 n.37. See *PPG Indus.*, 75 F.3d at 1564 (“a considerable amount of experimentation is permissible, if it is merely routine”).

3. The Common Structural Features Claimed by the Wilton Patents Set Them Apart from Cases Cited by NS

The *Amgen*, *Baxalta*, *Idenix*, and *Wyeth* cases cited by NS are inapposite. See Br-1 at 17-20. In each, the patent at issue failed to disclose any structural features that a POSA could utilize to arrive at compounds having the claimed function. See *Amgen*, 598 U.S. at 614 (the patents

forced researchers “to engage in painstaking experimentation to see what works”); *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1366 (Fed. Cir. 2023) (the patent did not disclose “any common structural (or other) feature delineating which antibodies will bind to Factor IX/IXa and increase procoagulant activity from those that will not.”); *Idenix*, 941 F.3d at 1161 (the patent only identified the “target” enzyme, not structural features of enzyme inhibitors); *Wyeth & Cordis Corp. v. Abbott Lab’ys*, 720 F.3d 1380, 1385 (Fed. Cir. 2013) (“The specification is silent about how to structurally modify sirolimus, let alone in a way that would preserve the recited utility.”). Because of this, the only way that a POSA could find claimed compounds in these cases was via trial-and-error experimentation.

The situation here is different. The Wilton Patents identify a set of structural criteria “running through” the claimed genus of ASOs, which a POSA could utilize to make ASOs that achieve the particular purpose of inducing exon 53 skipping. *See supra* §§ III.B, III.C.1.a; *Amgen*, 598 U.S. at 611. As the Supreme Court acknowledged, the specification need only disclose “some general quality running through the class that gives it a peculiar fitness for the particular purpose.” *Amgen*, 598 U.S. at 611 (citation omitted). Here, the disclosed and claimed structural features “reliably enable a person skilled in the art to make and use all of what is claimed.” *See id.*

NS’s attempt to analogize this case to the “conservative substitution” theory discussed in *Amgen* is misplaced for multiple reasons. *See* Br-1 at 19-20. For one thing, the claim scope is different. The claims in *Amgen* were broadly drawn to antibodies using purely functional language—seeking to claim “an entire universe of antibodies.” *Amgen*, 598 U.S. at 603, 613. Here, the claims are structurally drawn to ASOs targeting a limited region of exon 53. *See supra* §§ III.B, III.C.1.a. Also, the technology is different. The “conservative substitutions” discussed in *Amgen* refers to making amino acid substitutions in an antibody, which has *unpredictable* results on

antibody activity. *Amgen*, 598 U.S. at 614. In contrast, ASOs for exon skipping work through a “true antisense” mechanism, where deviations from the hot spot sequence predictably decrease activity. *See supra* §§ III.B, III.C.1.a. Finally, the patents are different. The exon 53 hot spot disclosed in the Wilton Patents provides a template target sequence for exon skipping ASOs. *See* Ex. 11, 186:2-15, 24:9-25:19; D.I. 427-2, ¶¶37-38. The *Amgen* patent provided no such roadmap. *Amgen*, 598 U.S. at 614.

NS’s motion, which ignores the stark differences between the technology involved here versus that in its cited cases, should be denied.

IV. OPPOSITION TO NS’S MOTION #2 (INFRINGEMENT OF NS PATENTS)

NS’s summary judgment motion for infringement of the NS Patents is moot in view of the joint stipulation regarding dismissal of certain claims and defenses filed January 8, 2024. D.I. 455, ¶¶1-2 (Sarepta stipulating to voluntary dismissal in part of its defense of no direct and/or no induced and contributory infringement of certain claims of the NS Patents while maintaining all other defenses and counterclaims, including those for invalidity, unenforceability, and no willful infringement of those claims). Sarepta requests denial of NS’s summary judgment motion as moot.

V. OPPOSITION TO NS’S MOTION #3 (BREACH OF CONTRACT)

A. Summary of Argument

Contrary to NS’s assertions, there has been no “stipulation” to the amount of damages for NS’s breach of contract claim—NS is merely offering to accept the upper limit of a range of damages figures presented by Sarepta’s expert. Sarepta did not stipulate to that figure. Instead, Sarepta continues to assert that the amount of damages awarded to NS if it were to prevail here should be far less than the upper limit calculated by its expert for two reasons: first, there remains a genuine dispute of material fact regarding the calculation of damages, which are based on the reasonableness of attorneys’ fees; and second, NS’s own material breach of the MCA limits its

recovery here. Thus, there remain disputes of material fact with respect to the amount of damages incurred by NS should it prevail on its claim, making summary judgment inappropriate.

B. Legal Standards

It is established Delaware law that in order to recover damages for a breach of a contract, the plaintiff must demonstrate substantial compliance with all of the provisions of the contract. *See Emmett S. Hickman Co. v. Emilio Capaldi Dev., Inc.*, 251 A.2d 571, 573 (Del. Super. Ct. 1969). Whether a party has substantially performed is usually a question of fact, making summary judgment “inappropriate.” *SLMSoft.Com, Inc. v. Cross Country Bank*, No. Civ.A.00C09163JRJ, 2003 WL 1769770, at *13 (Del. Super. Ct. Apr. 2, 2003).

C. Summary Judgment Regarding NS’s Breach of Contract Claim Is Improper

1. There Remains a Genuine Dispute of Material Fact

Summary judgment regarding NS’s breach of contract claim should be denied because there remains a dispute over the amount of alleged damages stemming from NS’s breach of contract claim. Br-3 at 1; D.I. 427-10, ¶¶198, 320; RSOF ¶3.1.

Under Delaware law, the amount of damages resulting from an alleged breach of contract is a material fact. *Jack Marine Int’l Servs. Ltd. v. Tilman Enters. Inc.*, No. 18-mc-349-MN, 2020 WL 3488434, at *5 (D. Del. June 26, 2020), *report and recommendation adopted sub nom. Jack Marine Int’l Servs. Ltd. v. Tillman Enters. Inc.*, No. 18-mc-349 (MN), 2020 WL 3960627 (D. Del. July 13, 2020). Such a factual dispute is genuine for the purposes of summary judgment “if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party.” *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011).

A dispute over the amount of damages, then, renders summary judgment inappropriate. *Jack Marine*, 2020 WL 3488434, at *5. Other courts, too, have found summary judgment inappropriate when the parties dispute the amount of damages that may be due a plaintiff. *See*

[REDACTED]

Precision Indus. v. Behnke Lubricants, Inc., 396 F. Supp. 2d 1012, 1019 (S.D. Iowa 2005) (denying motion for summary judgment because “there is a genuine issue of material fact in dispute regarding the amount of money that is due”); *Nissan N. Am. Inc. v. Schrader Elecs., Ltd.*, No. 3:13-CV-180, 2014 WL 5410296, at *11 (M.D. Tenn. Oct. 23, 2014) (denying motion for summary judgment when damages were based on legal fees and genuine issues of material fact as to the reasonableness of the moving party’s legal expenses “must be resolved by a jury”).

Summary judgment is inappropriate here because there remains a genuine dispute regarding the amount of alleged damages stemming from NS’s breach of contract claim. Sarepta’s damages expert, Mr. Jarosz, calculated that if NS were to prevail on this claim, damages would be [REDACTED]. D.I. 427-10, ¶¶198, 320; RSOF ¶3.1. Mr. Jarosz calculated this range by correcting flaws in the analysis of Mr. Hosfield, NS’s damages expert. *Id.*, ¶¶ 194-98.

NS now attempts to make a one-sided “stipulation” to a figure of \$ [REDACTED] in damages for its breach of contract claim to try to argue that there is “no dispute regarding damages.” Br-3 at 1. But *Sarepta* did not stipulate that the *upper limit* calculated by its expert is the correct amount of damages. RSOF ¶3.1. Sarepta continues to assert that the correct amount of damages is much lower. In *Precision Industries*, the parties disputed the amount of money owed, and for which goods the sum was owed. 396 F. Supp. 2d at 1019. The non-movant asserted that the relevant damages were not what the movant presented. *Id.* (the movant presenting a debt of \$73,099.91 and the non-movant asserting knowledge of “less than \$73,099.91 in debt outstanding”). The court found this to be a genuine dispute and denied summary judgment. *Id.*

Further, the damages stemming from Sarepta’s alleged breach of contract are based on NS’s claimed attorney’s fees. Br-3 at 1, 6. Other courts have denied summary judgment when damages are based on legal fees and the parties disagreed about the reasonableness of those fees.

See *Nissan N. Am. Inc.*, 2014 WL 5410296, at *11 (holding that genuine issues of material fact as to the reasonableness of the moving party's legal expenses "must be resolved by a jury"). Here, Mr. Jarosz has raised the same issue of the reasonableness of the legal fees claimed by NS, issues which "must be resolved by a jury." D.I. 427-10, ¶¶194-98; *Nissan N. Am. Inc.*, 2014 WL 5410296, at *11. Because a jury could find the relevant damages for NS's breach of contract claim to be less than \$ [REDACTED], there remains a genuine dispute over a material fact and summary judgment is inappropriate. *Lamont*, 637 F.3d at 181.

2. NS's Own Breach Limits Its Remedy

Further, NS's own breach of the MCA limits its remedy here. Judge Stark found that NS materially breached its obligations under the MCA and granted Sarepta preliminary relief. RSOF ¶¶3.2-3.7; Ex. 2, 31-34; D.I. 84. It is established Delaware law that in order to recover damages for a breach of contract, the plaintiff must demonstrate substantial compliance with all of the provisions of the contract. See *Emmett S. Hickman Co.*, 251 A.2d at 573. A determination of whether a party has substantially performed is "clearly" a question of fact, making summary judgment on the issue inappropriate. *SLMSOft.Com*, 2003 WL 1769770, at *13.

NS has not demonstrated that it has substantially complied with the MCA. Indeed, in light of its own breach, NS *cannot* demonstrate substantial compliance. NS materially breached its obligations under the MCA when it included confidential information in both its original Complaint and then again in its First Amended Complaint in this action. RSOF ¶¶3.2-3.7; D.I. 1, 39. Judge Stark already found that NS violated the confidentiality and non-use provisions of the MCA and struck the offending statements from its pleadings. RSOF ¶¶3.6-3.7; Ex. 2, 31-34; D.I. 84. NS's repeated breach at least creates a question of fact for the jury of whether NS has substantially complied with the MCA.

Courts in Delaware and other courts applying Delaware law have denied summary judgment on such a claim when faced with evidence that a breach-of-contract plaintiff also breached the contract at issue. *See MD Helicopters Inc. v. Boeing Co.*, No. CV-17-02598-PHX-JAT, 2019 WL 3840974, at *11 (D. Ariz. Aug. 15, 2019) (after the defendant presented evidence of the plaintiff's own breach, declining to grant summary judgment on breach of contract because "there is a genuine dispute of material fact as to whether [the plaintiff] substantially performed its contractual obligations.") (applying Delaware law); *Edelstein v. Goldstein*, C.A. No. 09C-05-034DCS, 2011 WL 721490, at *5 (Del. Super. Ct. Mar. 1, 2011) (denying motion for summary judgment based on genuine issue of material fact surrounding substantial compliance).

In light of its own breach of the MCA, there remain at minimum questions of material fact as to whether or not NS has substantially complied with *all of the provisions* of the contract at issue. This is fatal to its motion.

VI. OPPOSITION TO NS'S MOTION #4 (NO ANTICIPATION OF CERTAIN NS PATENT CLAIMS)

A. Summary of Argument

NS advances a one-sided view of the facts in its summary judgment of no anticipation, but on summary judgment, the facts must be viewed in the light most favorable to the non-moving party, Sarepta. NS offers a superficial analysis that is little more than a word search, ignoring Sarepta's evidence of what a POSA would reasonably understand Popplewell '212 (Ex. 18) to disclose. The claims at issue⁸ are generally directed to a 25-nucleotide (*i.e.*, "25-mer") PMO that is 100% complementary to the (+36+60) region of exon 53 in human dystrophin and has a 5'-TEG modification. *See* D.I. 427-1, ¶¶185, 335, 353, 362; D.I. 427-3, ¶¶25, 49. NS's only argument is

⁸ NS's motion is only directed to claim 3 of the '092 Patent, claim 2 of the '461 Patent, and claims 1-4 of the '217 Patent. NS does not move with respect to claims 1-2 of the '092 Patent, claim 1 of the '461 Patent, claims 1-2 of the '106 Patent, and claims 1-12 of the '741 Patent.

that Popplewell '212 “does not *disclose*” one claimed feature—the 5'-TEG modification. But NS focuses solely on whether Popplewell '212 specifically uses the words “5'-TEG.” NS ignores the “dispositive question” for purposes of anticipation, *i.e.*, whether a POSA would “reasonably understand or infer” from Popplewell '212 that “every claim limitation is disclosed in that single reference.” *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1373 (Fed. Cir. 2020). Here, a POSA would know that exon-skipping PMOs must have a 5' end. A POSA would also understand that the PMO of Popplewell '212 must include one of three 5'-end groups known at the time for exon-skipping PMOs, one of which was 5'-TEG, and would “at once envisage” 5'-TEG. NS's mere disagreement with Sarepta's evidence does not suffice to avoid trial on the issue. A jury must decide which expert to credit and whether a POSA would reasonably understand or infer from Popplewell '212 that it discloses the claimed PMO having a 5'-TEG modification.

B. Legal Standard

To anticipate, the prior art need not use exactly the same words as the claims. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009); *see Acoustic Tech.*, 949 F.3d at 1373 (“In an anticipation analysis, the dispositive question is whether a skilled artisan would ‘reasonably understand or infer’ from a prior art reference that every claim limitation is disclosed in that single reference.”); *VirnetX Inc. v. Apple Inc.*, No. 2022-1523, 2023 WL 6933812, at *4 (Fed. Cir. 2023) (non-precedential) (“This court has made clear that a reference can anticipate, *even when it does not expressly recite a claimed limitation*, if a person of ordinary skill in the art ‘would reasonably understand or infer from the prior art reference’s teaching that every claim [limitation] was disclosed in that single reference.’”); *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1340 (Fed. Cir. 2020); *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991). “Expert testimony may shed light on what a skilled artisan would reasonably understand or infer from a prior art reference.” *Acoustic Tech.*, 949 F.3d at 1373.

C. Argument

Popplewell '212 discloses the claimed 25-mer "PMO" that is 100% complementary to the (+36+60) region of exon 53 in human dystrophin, and NS does not contend otherwise in its motion.⁹ See, e.g., D.I. 427-1, ¶299; D.I. 427-3, ¶25; RSOF ¶4.1. As of the earliest possible effective filing date of the claims at issue (August 2011), a POSA would know that each "PMO" in Popplewell '212 must necessarily include a 5'-end group. See D.I. 427-1, ¶113; D.I. 427-3, ¶51; RSOF ¶4.2. A POSA at the time would also "at once envisage" 5'-TEG as one of only three choices of 5'-end group (along with an amide group and a hydroxyl group) for exon-skipping PMOs.¹⁰ *Id.*; RSOF ¶4.3. Because that genus is "so limited that a person of ordinary skill in the art can 'at once envisage each member of this limited class,'" it is a disclosure of the 5'-TEG modification for purposes of anticipation. *In re Gleave*, 560 F.3d at 1338.

Contrary to NS's argument, Sarepta is not "using the knowledge of a POSA to fill in a limitation that is missing from '212 Popplewell." Br-4 at 2. Instead, a POSA would reasonably understand and infer that Popplewell '212 discloses the claimed PMO with a 5'-TEG modification. See *VirnetX*, 2023 WL 6933812, at *4 (rejecting argument that limitation was missing from a prior art reference; limitation "would be understood to be disclosed by the [prior art] reference, even though not expressly stated as such in the reference itself"); *Acoustic Tech.*, 949 F.3d at 1373; *Genentech*, 946 F.3d at 1340; *In re Baxter*, 952 F.2d at 390.

⁹ Indeed, NS's expert, Dr. Hastings, unambiguously identifies this PMO in her analysis of Popplewell '212. D.I. 427-6, ¶51, Table 1; D.I. 427-3, ¶26.

¹⁰ In her expert reports, Dr. Hastings does not dispute that a POSA would at once envisage these three 5'-end groups, or that a POSA would have been particularly interested in a PMO with a 5'-TEG modification because of the unique advantages of that modification. See D.I. 427-1, ¶113 ("In addition to its proven safety profile as reported in Sazani 2010, the TEG modification was believed to confer improved solubility and stability to PMOs."); RSOF ¶4.4. Instead, she merely provides her incomplete understanding of the law, *i.e.*, that a "POSA is not permitted to fill in any missing limitations even if they can immediately envisage them." D.I. 427-6, ¶173.

NS is incorrect that Dr. Dowdy “openly admits that ’212 Popplewell does not disclose a PMO with the claimed 5’-TEG limitation.” Br-4 at 3. Dr. Dowdy merely acknowledges that Popplewell ’212 does not “expressly” refer to the 5’-TEG modification, *i.e.*, it does not use the words “5’-TEG.” But that does not end the anticipation analysis, because anticipation does not require verbatim disclosure of each claim limitation. *See, e.g., In re Gleave*, 560 F.3d at 1334 (“the reference need not satisfy an *ipsissimis verbis* test”).

Dr. Dowdy opined that a POSA would understand the disclosure of the relevant “PMO” in Popplewell ’212 to include a 5’-TEG as one of three possible choices for exon-skipping PMOs. *E.g.*, Ex. 11, 124:8-10 ([REDACTED]). Notably, NS selectively quotes only a portion of Dr. Dowdy’s answer to a question at deposition (Br-4 at 3) and omits his testimony that [REDACTED] Ex. 11, 124:3-4.

The cases NS relies on – *Nidec*, *Galderma*, *Plexxikon* – are inapposite because they all involve situations where a limitation is entirely missing from the asserted prior art reference. Here, a POSA would know that exon-skipping PMOs have a 5’ end and that the TEG modification was a particularly prominent choice (out of only three) for that end. The facts are analogous to *In re Baxter*, where the Federal Circuit affirmed a finding of anticipation even though the prior art did not expressly disclose one of the claim limitations. In that case, the claims were directed to a multiple blood bag system, including a “DEHP-plasticized primary bag.” 952 F.2d at 389. The asserted prior art only referenced a certain commercial system, but there was “no express reference to DEHP.” *Id.* at 390. The Federal Circuit affirmed the finding of anticipation, because “it is clear that one skilled in the art would have known that Becker was referring to a DEHP-plasticized primary bag.” *Id.* In this case, as in *In re Baxter*, a POSA would understand that Popplewell ’212

[REDACTED]

discloses the claimed PMO with a 5'-TEG modification, regardless of whether there is an express reference to 5'-TEG. At the very least, there is a question of material fact on this point, and the Court should deny NS's motion for partial summary judgment.

VII. OPPOSITION TO NS'S MOTION #5 (NO INEQUITABLE CONDUCT)

A. Summary of Argument

The Court should deny NS's motion for partial summary judgment of no inequitable conduct because the single most reasonable inference from the evidence is that NS acted with deceptive intent when it knowingly (and repeatedly) withheld material information from the PTO during prosecution. For example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Similarly, [REDACTED]

[REDACTED]

[REDACTED] The evidence further reveals a pattern of [REDACTED]
[REDACTED] to obtain issuance of the claims. The only reasonable inference is that NS, and Mr. Watanabe specifically, intended to deceive the PTO into granting the NS patents.

NS ignores the evidence of [REDACTED] and asserts, without factual support, that summary judgment is appropriate because there are "[o]ther reasonable interpretations of Sarepta's evidence." Br-5 at 2. But that requires assuming facts NS does not identify as evidence and interpreting those non-identified facts in NS's favor. This is the opposite of what the Court must do at summary judgment, which is to address the evidence *of record* in the light most favorable to Sarepta.

Further, as NS's own paper illustrates, the parties dispute multiple material facts: (1) whether [REDACTED] are cumulative (they are not);

[REDACTED]

(2) whether [REDACTED] are but-for material (they are); and (3) whether [REDACTED] is cumulative (it is not). Disputes as to the interpretation of evidence—like those here—are bedrock reasons to deny summary judgment.

B. Additional Legal Standards

At summary judgment, Sarepta need only identify enough evidence so that, at trial, “a factfinder *could reasonably conclude* that deceptive intent is the single most reasonable inference” or that withheld information is but-for material. *Sysmex Corp. v. Beckman Coulter, Inc.*, Case No. 19-1642-JFB-CJB, 2022 WL 1503987, at *4 (D. Del. May 6, 2022), *report and recommendation adopted*, 2022 WL 1744573 (D. Del. May 31, 2022)).

C. Argument

1. Ample Evidence Shows NS’s Specific Intent to Deceive

NS ignores the bulk of the evidence Sarepta identified showing the single most reasonable inference is that NS intended to deceive the PTO [REDACTED] NS cites no evidence at all for its claims that Sarepta’s evidence of intent shows only (1) [REDACTED] (2) they knew it had been withheld; and (3) “someone should have known that information was material. *See* SOF ¶ 1.” Br-5 at 2. NS’s SOF ¶1 only proposes “Sarepta and UWA have alleged two bases for their inequitable conduct allegations,” citing only nine paragraphs of Sarepta’s Counterclaims (¶¶214-218 & 227-230) and four paragraphs from Sarepta’s technical expert, Dr. Dowdy, for support. D.I. 416 ¶1.

NS omitted citation to paragraphs 219-226 of Sarepta’s Counterclaims (D.I. 328) in its SOF ¶1, where Sarepta set forth facts citing testimony and documentary evidence that describe,

[REDACTED]

for example, [REDACTED]” to the PTO (§226) despite drafting parts of the NS patents’ specification and being involved in prosecution (§§219-225), that [REDACTED] (§§219-225), and how the single most reasonable inference from this pattern “ [REDACTED] (§226).¹¹ See RSOF §5.1 (reciting this, and additional, testimony and documentary evidence). This pattern included, for example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] RSOF §§5.1-5.4.

[REDACTED]

[REDACTED]

[REDACTED]¹² RSOF §§5.1, 5.5; *see also* D.I. 427-1, §§656-668 (and evidence cited therein).

[REDACTED]

[REDACTED] ASO. Ex. 9, 211:10-15, 43:15-44:7, 214:20-215:4; *see also* D.I. 427-1, §§656-668. Despite directly undermining the argument of purported superiority that secured allowance of NS’s claims, [REDACTED]

¹¹ Sarepta also identified evidence showing that attorneys in the U.S. and Japan involved in prosecuting the NS Patents specifically intended to deceive the PTO. *See, e.g.*, D.I. 328 §§175-178, 219-226 (and evidence cited therein); Ex. 10, 22:15-17, 22:24-23:18, 24:9-25:15. Sarepta intends to present this evidence at trial but does not do so here as its evidence regarding Mr. Watanabe is sufficient to deny summary judgment.

¹² NS criticizes Sarepta for not relying on Mr. Hirshfeld (“Sarepta’s expert on PTO practice and procedure”) and instead relying on Dr. Dowdy (technical expert). Br-5 at 2. As Sarepta explains in its concurrently filed Opposition to NS’s *Daubert* motions, NS’s criticism is legally incorrect, and Sarepta is entitled—and should be allowed—to rely on Dr. Dowdy’s opinions addressing the technical issues relating to inequitable conduct.

See D.I. 427-28, NS00000793; *see also* D.I. 472-1, ¶¶708-735 (Dr. Dowdy explaining this data [REDACTED] in Japan and Europe and [REDACTED] it from those offices). As the Federal Circuit has recognized, “[p]artial disclosure of material information about the prior art to the PTO cannot absolve a patentee of intent if the disclosure is intentionally selective,” as here. *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1190 (Fed. Cir. 2014).

There is more than sufficient evidence for a reasonable jury to conclude that the single most reasonable inference to be drawn from [REDACTED] [REDACTED] intended to deceive the PTO into granting the NS patent claims.¹³

2. There Are Genuine Disputes of Material Fact Regarding But-For Materiality

NS claims three facts are “undisputed,” but it does so by ignoring Sarepta’s evidence. D.I. 415 at 2. First, Sarepta disputes that the data withheld from the NS Patents and the PTO is “cumulative,” and, as discussed *supra* § VII.C.1, has provided extensive evidence showing it is *not* cumulative. Notably, [REDACTED] [REDACTED] was cumulative to information disclosed to the PTO. *See generally* Br-5.

¹³ NS cites *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc) to argue that because it alleges there are “[o]ther reasonable interpretations of Sarepta’s evidence,” NS is entitled to summary judgment. Br-5 at 2. That is incorrect. *Therasense* was decided after a bench trial. *Therasense*, 649 F.3d at 1285. At summary judgment the question is whether, viewed in the light most favorable to Sarepta as the non-moving party, there is enough evidence so that, at trial, “a factfinder *could reasonably conclude* that deceptive intent is the single most reasonable inference.” *Sysmex*, 2022 WL 1503987, at *4. As discussed above, Sarepta more than meets this correct standard.

[REDACTED]

Second, substantial evidence shows that NS could not have convinced the PTO to issue the NS patent claims but-for its [REDACTED]

[REDACTED] During prosecution, the examiner rejected NS's claimed ASOs as obvious over ASOs in the prior art Sazani '591 and Popplewell '212 references, explaining that they disclosed "oligomers targeting the same target site a[s] the instant invention." *See, e.g.*, D.I. 427-28, NS00000778. In the response that secured allowance of NS's claims, NS argued that the claimed ASO "had superior skipping effects over the exemplary oligomers taught in Popplewell ['212] and Sazani ['591], particularly the top performer taught in Popplewell ['212]." *Id.*, NS00000793; *see also id.* at -788 (only amendment deleted "SEQ ID NO: 11" from claims). Had [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See, e.g., supra* § VII.C.1; D.I. 427-1, ¶¶633-638, 650-676; *see also id.* ¶¶420, 417-621 (explaining NS's patent claims are at least obvious over Popplewell 2010 and Sazani 2010), ¶744 (noting Sazani 2010 was not submitted to the PTO).

Third, Sarepta also contests NS's assertion that the Sazani 2010 reference is cumulative. As Dr. Dowdy explained, Sazani 2010 contains—all in one reference—additional disclosures to those of the prior art of record, including genotoxicity and pharmacology safety studies. RSOF ¶5.6. Moreover, [REDACTED]

[REDACTED]

[REDACTED] RSOF ¶5.7. Yet, [REDACTED]

[REDACTED] NS's patents'

specification that [REDACTED] otherwise provide it to the PTO. RSOF ¶5.8. Finally, it is readily apparent that the parties dispute whether Sazani 2010 is cumulative given that both sides submitted significant technical expert testimony on the issue. *Compare* D.I. 427-1, ¶¶745-748; D.I. 427-6, ¶¶248-260; D.I. 427-3, ¶¶162-180; *see Pact XPP Schweiz AG v. Intel Corp.*, Case No. 1:19-cv-01006-JDW, 2023 WL 2631503, at *7 (D. Del. Mar. 24, 2023) (disputes of material fact were sufficient to deny summary judgment where “Intel’s expert will testify that the reference was not cumulative of others provided to the PTO, and that it would have been material”).

D. Conclusion

For the foregoing reasons, Sarepta respectfully requests the Court deny NS’s motion for partial summary judgment regarding no inequitable conduct.

VIII. CONCLUSION

For the reasons discussed above, NS’s motions for summary judgment should be denied.

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January 12, 2024

CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 12, 2024, upon the following in the manner indicated:

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